

**IN THE CLAIMS**

Claims 1, 3, 5, 6, 19, 32, 41, and 43 have been amended. Claims 4, 9, and 46-56 are canceled without acquiescence or prejudice. New claims 57-81 have been added.

1. (Currently Amended) A computer implemented method for classifying analyzing chromatograms, comprising:

receiving a first chromatogram data corresponding to a first chromatogram;

adjusting the first chromatogram data in a first region of interest by centering an analysis window around one or more trace features in the first region of interest;

reducing the first chromatogram data to a first data set, based at least on an average time for the chromatogram data in the first region of interest by determining an integral of the first chromatogram data and plotting against a time axis, determining a set of time points, and forming arrays of first data set values based upon the set of time points and corresponding integral values for the set of time points;

receiving a second chromatogram data corresponding to a second chromatogram;

adjusting the second chromatogram data in a second region of interest by centering an analysis window around one or more trace features in the second region of interest;

reducing the second chromatogram data to a second data set based at least on an average time for the chromatogram data in the second region of interest by determining an integral of the second chromatogram data and plotting against a time axis, determining a set of time points, and forming arrays of first data set values based upon the set of time points and corresponding integral values for the set of time points; and

comparing the first data set and the second data set to produce a comparison result; and

classifying the first and second chromatograms based on the comparison result.

2. (Original) The method of claim 1 in which the acts of adjusting the first and second chromatogram data comprise baseline correction.
3. (Currently Amended) The method of claim 1 further comprising:  
identifying the first region of interest in the first chromatogram data before adjusting the first chromatogram data; and  
identifying the second region of interest in the second chromatogram data before adjusting the second chromatogram data.
4. (Canceled)
5. (Currently Amended) The method of claim 1 ~~claim 4~~ in which the act of centering comprises:  
determining an average time for the given region of interest; and  
centering the analysis window around the average time.
6. (Currently Amended) The method of claim 1 further comprising:  
filtering the first and second chromatogram data to identify ~~bad~~ flawed data.
7. (Previously Presented) The method of claim 6 in which the filtering is based upon criteria selected from a group consisting of peak height, peak area, peak shape, peak position, peak slope, and peak size.

8. (Original) The method of claim 1 in which the acts of reducing the first and second chromatogram data to the first and second data sets comprise determining arrays of data set values directly from the first and second chromatogram data.
9. (Canceled)
10. (Previously Presented) The method of claim 1 further comprising:  
selecting a reference chromatogram to be compared with one or both of the first and second chromatogram data.
11. (Original) The method of claim 10 in which the reference chromatogram is selected based upon first selecting a plurality of chromatograms having one or more identified characteristics that most closely match one or more reference characteristics, and identifying a single chromatogram within the plurality of chromatograms to be the reference chromatogram.
12. (Previously Presented) The method of claim 10 in which one or both of the first and second chromatogram data are compared against the reference chromatogram.
13. (Previously Presented) The method of claim 12 further comprising:  
mapping results of comparing the reference chromatogram against one or both of the first and second chromatogram data.

14. (Original) The method of claim 13 in which mapping is performed to a two-dimensional cluster map.
15. (Original) The method of claim 1 in which the act of comparing comprises determining a degree of similarity between the first and second data sets.
16. (Original) The method of claim 1 in which the act of comparing comprises determining a degree of dissimilarity between the first and second data sets.
17. (Original) The method of claim 1 in which the act of comparing comprises determining distance between vectors associated with the first and second data sets.
18. (Original) The method of claim 1 in which the first and second chromatogram data relate to DNA analysis, wherein the reduced chromatogram data excludes a main DNA peak and fully encapsulate a possible sequence variation peak.
19. (Currently Amended) A system for classifying ~~analyzing~~ chromatograms, comprising:
  - a data storage device to store chromatogram data;
  - a communications interface adaptable to receive chromatogram data from the data storage device;
  - a data adjustment module to adjust the chromatogram data;
  - a reduction module to reduce the chromatogram data to a data set based at least on an average time for the chromatogram data in a region of interest; and

a comparison module to compare the reduced data set against ~~the~~ other chromatogram data sets; and

a classification module to classify the chromatogram corresponding to the reduced data set.

20. (Previously Presented) The system of claim 19 further comprising a data filter.
21. (Previously Presented) The system of claim 20 in which the data filter performs filtering based upon criteria selected from the group consisting of peak height, peak area, peak shape, peak position, peak slope, and peak size.
22. (Original) The system of claim 19 in which the data adjustment module performs baseline correction for the chromatogram data in a region of interest.
23. (Original) The system of claim 19 in which the data adjustment module centers the analysis window around one or more trace features in a region of interest.
24. (Original) The system of claim 19 in which the reduction module determines an array of data set values directly from the chromatogram data.
25. (Original) The system of claim 24 in which the array of data set values are formed by:
  - selecting a set of time points in the first and second chromatogram data;
  - determining amplitude values corresponding to the set of time points; and
  - forming the arrays of data set values based upon the set of time points and their

corresponding amplitude values.

26. (Original) The system of claim 19 in which the reduction module determines an array of data set values based upon:

determining an integral of the chromatogram data and plotting against a time axis;

determining a set of time points;

forming the arrays of data set values based upon the set of time points and corresponding integral values for the set of time points.

27. (Original) The system of claim 19 implemented using one or more programmable logic devices.

28. (Original) The system of claim 19 further comprising a mapping module to map results from the comparison module.

29. (Original) The system of claim 28 further comprising a user interface to display results from the comparison module.

30. (Withdrawn) A method for automated classification of chromatograms, comprising:

collecting a first chromatogram data;

identifying a first qualitative characteristic for the first chromatogram data;

collecting a second chromatogram data;

identifying a second qualitative characteristic for the second chromatogram data; and

automated comparison of the first qualitative characteristic of the first chromatogram data to the second qualitative characteristic of the second chromatogram data to classify chromatograms.

31. (Withdrawn) The method of claim 30 in which the first and second qualitative characteristics of the first and second chromatogram data comprises peak shape.

32. (Withdrawn – Currently Amended) The method of claim 30 further comprising:  
adjusting data from the first chromatogram;  
reducing the first chromatogram data to a first data set, wherein the first chromatogram is reduced based on a consistent positioning across chromatograms;  
adjusting data from the second chromatogram;  
reducing the second chromatogram data to a second data set, wherein the second chromatogram data is reduced based upon the consistent positioning across chromatograms.

33. (Withdrawn) The method of claim 32 in which the acts of adjusting data from the first and second chromatograms comprise re-centering an analysis window.

34. (Withdrawn) The method of claim 30 further comprising:  
baseline correction of the first and second chromatogram data.

35. (Withdrawn) The method of claim 30 in which the first and second chromatograms comprise DHPLC chromatograms.

36. (Withdrawn) A method for classifying chromatograms, comprising:  
receiving a first DHPLC chromatogram;  
receiving a second DHPLC chromatogram;  
automated comparison between the first DHPLC chromatogram and the second DHPLC chromatogram; and  
classifying the first DHPLC chromatograms based upon the results of the automated comparison.
37. (Withdrawn) The method of claim 36 wherein the automated comparison is based upon qualitative analysis.
38. (Withdrawn) The method of claim 37 in which the qualitative analysis comprises analysis of peak shape.
39. (Withdrawn) The method of claim 36 in which the first DHPLC chromatogram is classified based upon likelihood of SNP in DNA corresponding to the first DHPLC chromatogram.
40. (Withdrawn) The method of claim 36 further comprising:  
mapping the first and second chromatogram data.
41. (Withdrawn – Currently Amended) The method of claim 36 further comprising:  
adjusting data from the first DHPLC chromatogram;  
reducing the first DHPLC chromatogram data to a first data set, wherein the first DHPLC



chromatogram is reduced based on a consistent positioning across chromatograms;

adjusting data from the second DHPLC chromatogram;

reducing the second DHPLC chromatogram data to a second data set, wherein the second chromatogram DHPLC data is reduced based upon the consistent positioning across chromatograms.

42. (Withdrawn) A user interface for displaying results of chromatogram analysis, comprising:

a cluster map display portion;

a raw chromatogram display portion; and

a normalized chromatogram display portion.

43. (Currently Amended) A computer usable medium having stored thereon a sequence of instructions which, when executed by a processor, causes the processor to execute a process for classifying chromatograms, said process comprising:

receiving a first chromatogram data corresponding to a first chromatogram;

adjusting the first chromatogram data in a first region of interest by centering an analysis window around one or more trace features in the first region of interest;

reducing the first chromatogram data to a first data set, based at least on an average time for the chromatogram data in the first region of interest by determining an integral of the first chromatogram data and plotting against a time axis, determining a set of time points, and forming arrays of first data set values based upon the set of time points and corresponding integral values for the set of time points;

receiving a second chromatogram data corresponding to a second chromatogram;

adjusting the second chromatogram data in a second region of interest by centering an

analysis window around one or more trace features in the second region of interest;

reducing the second chromatogram data to a second data set, based at least on an average time for the chromatogram data in the second region of interest by determining an integral of the second chromatogram data and plotting against a time axis, determining a set of time points, and forming arrays of second data set values based upon the set of time points and corresponding integral values for the set of time points; and

comparing the first data set and the second data set to produce a comparison result; and  
classifying the first and second chromatograms based on the comparison result.

44. (Previously Presented) The method of claim 1, further comprising determining the average time for chromatogram data in the first region of interest, and determining the average time for chromatogram data in the second region of interest.

45. (Previously Presented) The method of claim 44, wherein the determining the average time for chromatogram data in the first and second regions of interest is performed based on

$$\bar{t} = (\sum_{i=0}^{i=n} y_i^2 * t_i) / \sum_{i=0}^{i=n} y_i^2 .$$

46-56. (Canceled)

57. (New) A computer implemented method for determining chromatogram consistency, the method comprising:

receiving a data set for a plurality of chromatograms;

normalizing the data set for a region of interest;  
normalizing the data set to eliminate variations in peak height;  
analyzing the data set to find a representative datum for one of the chromatograms that can act as a reference;  
comparing the distribution of each chromatogram datum as a function of time relative to the reference; and  
determining whether each chromatogram datum of the data set is consistent or inconsistent with the reference based on the comparison.

58. (New) The method of claim 57, in which the data set for the chromatograms relates to DNA analysis, wherein each datum of the data set excludes a main DNA peak and fully encapsulates a possible sequence variation peak.

59. (New) The method of claim 57, wherein normalizing the data set for a region of interest comprises eliminating variations in retention time.

60. (New) The method of claim 57, wherein normalizing the data set to eliminate variations in peak height comprises:

determining an integral of each chromatogram datum and plotting against a time axis;  
determining a set of time points; and  
forming arrays of values based upon the set of time points and corresponding integral values for the set of time points for each chromatogram datum.

61. (New) The method of claim 57 further comprising determining an average time for each chromatogram datum.

62. (New) The method of claim 61, wherein determining the average time for each

chromatogram datum is performed based on  $\bar{t} = (\sum_{i=0}^{i=n} y_i^2 * t_i) / \sum_{i=0}^{i=n} y_i^2$ .

63. (New) The method of claim 57 in which the act of comparing comprises determining a degree of similarity between each datum and the reference.

64. (New) The method of claim 57 in which the act of comparing comprises determining a degree of dissimilarity between each datum and the reference.

65. (New) The method of claim 57 in which the act of comparing comprises determining distance between vectors associated with each datum and the reference.

66. (New) The method of claim 57 in which the control is selected based upon first selecting a plurality of chromatograms having one or more identified characteristics that most closely match one or more reference characteristics, and identifying a single chromatogram within the plurality of chromatograms to be the control.

67. (New) The medium of claim 43 in which adjusting the first and second chromatogram data comprise baseline correction.

68. (New) The medium of claim 43 wherein the process further comprises:  
identifying the first region of interest in the first chromatogram data before adjusting the first chromatogram data; and  
identifying the second region of interest in the second chromatogram data before adjusting the second chromatogram data.
69. (New) The medium of claim 43 in which centering comprises:  
determining an average time for the given region of interest; and  
centering the analysis window around the average time.
70. (New) The medium of claim 43 wherein the process further comprises:  
filtering the first and second chromatogram data to identify flawed data.
71. (New) The medium of claim 70 in which the filtering is based upon criteria selected from a group consisting of peak height, peak area, peak shape, peak position, peak slope, and peak size.
72. (New) The medium of claim 43 in which reducing the first and second chromatogram data to the first and second data sets comprise determining arrays of data set values directly from the first and second chromatogram data.
73. (New) The medium of claim 43 wherein the method further comprises:  
selecting a reference chromatogram to be compared with one or both of the first and second

chromatogram data.

74. (New) The medium of claim 73 in which the reference chromatogram is selected based upon first selecting a plurality of chromatograms having one or more identified characteristics that most closely match one or more reference characteristics, and identifying a single chromatogram within the plurality of chromatograms to be the reference chromatogram.

75. (New) The medium of claim 73 in which one or both of the first and second chromatogram data are compared against the reference chromatogram.

76. (New) The medium of claim 75 wherein the process further comprises:

mapping results of comparing the reference chromatogram against one or both of the first and second chromatogram data.

77. (New) The medium of claim 76 in which mapping is performed to a two-dimensional cluster map.

78. (New) The medium of claim 43 in which comparing comprises determining a degree of similarity between the first and second data sets.

79. (New) The medium of claim 43 in which comparing comprises determining a degree of dissimilarity between the first and second data sets.

80. (New) The medium of claim 43 in which comparing comprises determining distance between vectors associated with the first and second data sets.

81. (New) The medium of claim 43 in which the first and second chromatogram data relate to DNA analysis, wherein the reduced chromatogram data excludes a main DNA peak and fully encapsulate a possible sequence variation peak.

**REMARKS**

Claims 1-29 and 43-56 stand rejected. Claims 1, 3, 5, 6, 19, 32, 41, and 43 have been amended. Claims 4, 9, and 46-56 are canceled. New claims 57-81 have been added. With entry of this amendment, claims 30-42 remain withdrawn.

Claims 1-18 and 43-45 stand rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph.

In the previous Office action, the examiner suggested that the section 112 1<sup>st</sup> paragraph rejection to claim 1 can be overcome by amending the claim to include the elements of dependent claims 4 and 9. Claim 1 as amended includes the elements of claims 4 and 9. Therefore, applicant submits that claim 1 as amended satisfies the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph. Given that claims 2-3, 5-8, 10-18, and 44-45 depend from claim 1 as amended, applicant submits that these claims satisfy the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph. Applicant submits that claim 43 as amended satisfies the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph. Given that new claims 67-81 depend from claim 43 as amended, applicant submits that these claims also satisfy 35 U.S.C. 112, 1<sup>st</sup> paragraph.

Claims 1-18 and 44-45 stand rejected under 35 U.S.C. 101.

Claim 1 has been amended to recite “classifying the first and second chromatograms based on the comparison result.” Therefore, applicant submits that claim 1 as amended satisfies the requirements of 35 U.S.C. 101. Given that claims 2-3, 5-8, 10-18, and 44-45 depend from claim 1 as amended, applicants submit that these claims also satisfy the requirements of 35 U.S.C. 101.

Claims 1-29 and 43-56 stand rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.



Claim 1 has been amended to recite “classifying the first and second chromatograms based on the comparison result.” Therefore, applicant submits that claim 1 as amended satisfies the requirements of 35 U.S.C. 112, 2<sup>nd</sup> paragraph. Given that claims 2-3, 5-8, 10-18, and 44-45 depend from claim 1 as amended, applicants submit that these claims also satisfy the requirements of 35 U.S.C. 112, 2<sup>nd</sup> paragraph. Applicants submit that claim 43 as amended satisfies the requirements of 35 U.S.C. 112, 2<sup>nd</sup> paragraph. Given that new claims 67-81 depend from claim 43 as amended, applicant submits that these claims also satisfy 35 U.S.C. 112, 2<sup>nd</sup> paragraph. Applicant submits that claims 19-29 as amended satisfy the requirements of 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

Claims 19-29 stand rejected under 35 U.S.C. 112, first paragraph.

The December 31, 2002 Office action stated that, under 35 U.S.C. 112, 1<sup>st</sup> paragraph, there are several factors to consider in determining whether undue experimentation is required to make and use the invention. The factors cited were a) the quantity of experimentation, b) the amount of information provided, c) the presence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in the art, g) the predictability of the art, and h) the breadth of the claims. Applicant submits that claim 19 as amended satisfies the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph, based on the disclosure as filed and further based on the eight factors cited in the December action, which are discussed as follows:

A. The quantity of experimentation needed to perform the functions of adjusting, reducing, and comparing data as disclosed by the application as filed and as recited in claim 19 as amended, is minimal. For computer software-related inventions, the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph are satisfied by a disclosure of the functions of the software. “This is because, normally,

writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed.” Fonar Corp. v. General Electric Co., 107 F.3d 1543.

B. The amount of information provided in the application as filed discloses the functions of claim 19 as amended. Writing a satisfactory program for implementing the functions of claim 19 as amended “is within the skill of the art, not requiring undue experimentation,” because the “functions have been disclosed.” Fonar, 107 F.3d 1543. Therefore, because a programmer of reasonable skill could write a satisfactory program with ordinary effort based on the disclosure, the enablement requirement is satisfied for claim 19 as amended. Northern Telecom v. Datapoint Corp., 908 F.2d 931.

C. The presence of working examples in the application as filed satisfies the enablement requirement. As long as the specification discloses at least one example for making and using the claimed invention, the enablement requirement is satisfied. In re Fisher, 427 F.2d 833. Failure to disclose other examples by which the claimed invention may be made does not render a claim invalid for lack of enablement. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524.

D. The nature of the invention, which is related to computer science, is predictable. For inventions involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. Ex Parte Hitzeman, 9 USPQ 1821 (CCPA 1987) and In re Fisher, 427 F.2d 833 (CCPA 1970).

E. The state of the prior art for data processing is predictable. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. M.P.E.P. § 2164.01. For computer software-related inventions, the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph

are satisfied if a programmer of reasonable skill can write a satisfactory program with ordinary effort based on the disclosure. Northern Telecom v. Datapoint Corp., 908 F.2d 931.

F. The relative skill of those in the art allows skilled programmers to create software that processes digital data based on the functions disclosed in the specification as filed and recited in claim 19 as amended, because writing code for software “is within the skill of the art; not requiring undue experimentation,” once its functions have been disclosed. Fonar Corp. v. General Electric Co., 107 F.3d 1543.

G. The predictability of the art, which is data processing, is high. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. Ex Parte Hitzeman, 9 USPQ 1821 (CCPA 1987) and In re Fisher, 427 F.2d 833 (CCPA 1970).

H. The breadth of the claims is appropriate. The claims to an invention can be framed as broadly as possible in light of the prior art, and such claims can be properly based on a disclosure in the specification of but a single embodiment. AMI Industries, Inc. v. EA Industries, Inc., 204 USPQ 568, 588 (1979). Therefore, the invention recited in claim 19 as amended satisfies the enablement requirement based on the disclosure as filed, because the specification as filed discloses at least one embodiment of the invention of claim 19 as amended.

Therefore, applicants submits that claim 19 as amended satisfies the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph. Given the fact that claims 20-29 depend from claim 19 as amended, applicant submits that these claims also satisfy the requirements of 35 U.S.C. 112, 1<sup>st</sup> paragraph.

New claim 57 has been added. Applicant respectfully submits that the art of record neither


discloses nor suggests the combination of elements recited in newly added claim 57. Therefore, applicant submits that new claim 57 is patentable. Given that new claims 58-66 depend from new claim 57, applicant submits that these claims are also patentable.

On the basis of the above remarks, reconsideration and allowance of the claims is believed to be warranted and such action is respectfully requested. If the Examiner has any questions or comments, the Examiner is respectfully urged to contact the undersigned at the number listed below.

Respectfully submitted,

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